Great Lakes Fish Monitoring Program

Quality Management Plan

Prepared by:
Elizabeth Murphy, Environmental Scientist
US EPA GLNPO
77 W. Jackson Blvd.
Chicago, Illinois 60604

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Quality Assurance Management Plan

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Elizabeth Murphy, Environmental Scientist
US EPA GLNPO
77 West Jackson Boulevard
Chicago, Illinois 60604

Approvals:

Louis Blume Quality Manager	Date
Elizabeth Murphy Great Lakes Fish Monitoring Program Manager	Date

Acronyms and Abbreviations

CRL	Central Regional Laboratory
CSP	Contaminants Surveillance Program
CSC	Computer Sciences Corporation
DCM	Document Control Manager
DNR	Department of Natural Resources
DQA	Data Quality Assessment
DQOs	Data Quality Objectives
EMIT	Environmental Monitoring & Indicators Team
EPA	Environmental Protection Agency
EPAAR	EPA Acquisition Regulations
FAR	Federal Acquisition Regulations
GLFL	Great Lakes Fishery Laboratory
GLFMP	Great Lakes Fish Monitoring Program
GLNPO	Great Lakes National Program Office
GLP	General Laboratory Practice
IAG	Interagency Agreement
IJC	International Joint Commission
LaMP	Lakewide Management Plans
LAN	Local Area Network
LMMB	Lake Michigan Mass Balance
MIRB	Monitoring, Indicators, and Reporting Branch
MQOs	Measurement Quality Objectives
NYDEC	New York Department of Environmental Conservation
OEI	Office of Environmental Information
PE	Performance Evaluation
PI	Principal Investigator
PO	Program Officer
PTD	Project Tracking Database
QA	Quality Assurance
QAARWP	Quality Assurance Annual Report and Workplan
QMP	Quality Management Plan
QAPP	Quality Assurance Project Plan
QC	Quality Control
QSA	Quality System Audits
RAP	Remedial Action Plans
RFP	Request for Proposals
SOP	Standard Operating Procedure
SOW	Statement or Scope of Work
TSA	Technical System Audit
USFDA	United States Food and Drug Advisory
USFWS	United States Fish and Wildlife Service
USGS-GLSC	United States Geological Survey – Great Lakes Science Center

Section 1
Quality Management and Organization

1.1 Introduction

The Environmental Protection Agency (EPA) Order 5360.1 A2 *Policy and Program Requirements for the Mandatory Agency-wide Quality System,* May 2000, establishes policy and program requirements for the preparation and implementation of quality management systems (GLNPO QMP at http://www.epa.gov/glnpo/qa/qmp/index.html). In support of this order, the EPA requires each environmental program to develop a quality management plan (QMP). The QMP is management's statement of the process that will govern the quality assurance (QA) and quality control (QC) activities for a given program. The QMP defines the program's QA-related policies, areas of application, roles, responsibilities and authorities of staff, and the management and technical practices that assure that environmental data used to support decisions are:

- of adequate quality and usability for their intended purpose, and
- where necessary, legally and scientifically defensible.

This document defines the Great Lakes Fish Monitoring Program's (GLFMP's) quality system. The GLFMP is an environmental program run by the Great Lakes National Program Office (GLNPO), designed to monitor contaminant trends in Great Lakes fish. GLNPO is a geographically-focused office, whose mission is to lead and coordinate United States efforts to protect and restore the Great Lakes. This QMP is a management tool that describes how GLNPO will plan, implement, document, and assess the GLFMP's ability to support its mission.

GLNPO management is responsible for ensuring that the QMP is implemented. In accordance with policies and procedures established under EPA Order 5360.1 A2 Section 7-b. Program Office Directors and Senior Managers shall:

a) Ensure that all Program components comply fully with the requirements of the Order;
b) ensure that quality management is implemented as prescribed in the organization's approved QMP;
c) ensure that the environmental data are of sufficient quantity and adequate quality for their intended use and are used consistent with such intentions;
d) perform periodic assessments of the GLFMP to determine the conformance of its mandatory quality system to its approved QMP and the effectiveness of its implementation;
e) ensure that deficiencies highlighted in the assessments are appropriately addressed;
f) identify QA and QC training needs for all participants in the GLFMP and provide for this training.

This QMP documents the GLFMP's quality system to meet these requirements in fulfilling its mission. The QMP is organized in the following seven sections:

- **Section 1** continues with a description of the GLFMP program, mission, organizational structure, and roles and responsibilities of GLFMP participants;
- **Section 2** describes the components of GLFMP's quality system, including a description

of the tools used by GLNPO staff and other GLFMP partners to implement the quality system;

- **Section 3** provides information regarding personnel qualifications and quality system training requirements;
- **Section 4** discusses GLFMP's process for procuring items and services and ensuring suppliers provide items and services that are of known and documented quality and meet associated technical requirements;
- **Section 5** provides information on the control and maintenance of documents and records and the GLFMP's process for managing information
- **Section 6** provides a description of GLFMP's policies and procedures for assessing the environmental information collected, and procedures for responding to those assessments;
- **Section 7** discusses GLFMP's ongoing activities towards improving quality throughout the program.

Each section is broken into a historical component and a current procedure component when necessary.

The Great Lakes Fish Monitoring Program QMP is supported by a Quality Assurance Project Plan (QAPP) for Sample Collection Activities (Appendix 1), which describes the QA/QC activities and procedures associated with collecting samples of fish tissue for the GLFMP, and a Quality Management Plan for Analysis of Fish Tissue, which outlines the quality assurance activities associated with the analytical component of this program (Appendix 1).

Current GLFMP Quality Documentation (Appendix 1), Historical GLFMP Quality Documentation (Appendix 2), GLFMP Program Design Documents and Significant Reports (Appendix 3), GLFMP Significant Events (Appendix 4), GLFMP Collection Information including collection grid maps, collector contact information, and changes in collectors overtime (Appendix 5), and a list of GLFMP publication (Appendix 6) accompany the QMP to provide insight into the original design and operation of the Great Lakes Fish Monitoring Program.

In accordance with the guidance provided in EPA Manual 5360 A1, this QMP is a dynamic document that is subject to change as the GLFMP progresses. This document will attempt to integrate both the historical aspects of the program and current activities to provide a rational for past decision and outline proper procedure for current day operation of the GLFMP. This QMP will be reviewed annually by the GLFMP Program Officer to determine if revision is required. In addition, as the GLFMP progresses in accordance with the continuous improvement philosophy, all changes to procedures described in this QMP will be reviewed by the GLNPO Quality Manager to determine if the changes significantly impact the quality objectives of the program. If changes are deemed to be significant, the QMP will be revised accordingly and distributed to the Monitoring, Indicators and Reporting Branch (MIRB) Chief, the Document Control Manager (DCM); and the Office of Environmental Information's (OEI) Quality Staff (Appendix 1).

In accordance with GLNPO's document control procedures, GLNPO's Quality Manager and DCM will maintain up to date versions of quality documentation on GLNPO's website, http://www.epa.gov/glnpo/qa/qmp/index.htm.

1.2 Quality Management Policy, Goals, and Objectives

The Great Lakes Fish Monitoring Program's Quality Management Plan is governed by the same principles guiding the quality management of the Great Lakes National Program Office, http://www.epa.gov/glnpo/qa/qmp/index.htm. GLNPO's quality management policy focuses on four operating principles: assistance, flexibility, value-added, and continuous improvement. The GLFMP operates under these same principles and works collaboratively with the quality team staff to ensure that the program will provide information of adequate quality to support environmental decisions.

The EPA project officer responsible for managing the GLFMP, along with the quality team staff, offers QA assistance to all participants in the GLFMP to ensure adherence to the GLFMP QAPPs during every phase of the program. GLFMP partners responsible for fish collection and processing must adhere to the Quality Assurance Project Plan for Sample Collection Activities (Appendix 1) during their sampling and processing procedures. Likewise the party responsible for the chemical analyses must adhere to the approved Quality Documentation that they submit prior to GLFMP sample analysis. The GLNPO quality program is flexible, in that all QA policies and requirements should provide added value to the GLFMP, rather than inhibit the program through unnecessary restraint. Annual sample collection requires flexibility in its SOPs due to the fact that in any given year, fish may not be present in sufficient abundance and collection location and/or sample number may be altered as a result. Quality documentation needs to be flexible enough to deal with these types of situations while maintaining value added to the GLFMP through continuous improvement and strengthening of the program through tighter QA controls. The primary goals and objectives of the GLFMP's quality management plan are to ensure that the program design and implementation is sufficient to meet the program's overall objectives.

The GLFMP plays an integral role in GLNPO's commitment and ability to protect the Great Lakes Ecosystem. GLNPO must make decisions regarding the quality of the environment and the health of wildlife and humans. These decisions usually depend on qualitative and quantitative measurements derived from various data collection activities. In fact the GLFMP has produced one of the most valuable long-term contaminant trend data sets in the Great Lakes. Decision makers must be able to use this data set with some level of confidence in order to make informed decisions. It is the policy of the Great Lakes National Program Office to ensure collected information is of adequate quality for the intended use. This Quality Management Plan for the GLFMP ensures that data collected from this program is of adequate quality to meet its goals and objectives of describing both qualitatively and quantitatively the health of the Great Lakes Ecosystem. The GLFMP quality management policy is implemented through a series of policies and practices that are described below.

Policies and Practices

Allocation of appropriate resources	GLNPO management will allocate adequate resources to meet the quality system goals and requirements outlined in this QMP for the GLFMP.
Inclusion of quality management in daily activities	It is GLFMP policy that the quality system must be implemented in the daily activities of all GLFMP partners. This policy is fostered through frequent interactions between the GLFMP Program Officer and staff from the GLFMP partners. The GLFMP steering committee meets via conference call biannually to discuss various issues regarding the program. Also, the GLFMP Program officer has been trained on the quality system philosophy, requirements, tools, and reference documents. In addition, GLNPO's Quality Manager is involved in a supporting role at the project level of the GLFMP.
Systematic planning	The GLFMP was originally designed to support a coordinated surveillance and monitoring program between the United States and Canada following the Great Lakes Water Quality Agreement. Fish were considered to be excellent integrators of aquatic ecosystems and thus could be used as indicators of overall ecosystem health. At the time that the GLFMP was planned, very little data existed to help with the planning of this long-term environmental monitoring program. Using the best available data, GLNPO and USFWS scientists mapped out the program objectives and strategy. As the program evolved and other objectives were added, the planning changed accordingly. These changes are documented in Appendix 4, S*ignificant Events of the Great Lakes Fish Monitoring Program* (Appendix 4).

Quality system documentation	The GLFMP has the appropriate quality system documentation in place: *Quality Assurance Project Plan for Sample Collection Activities, Trends in Great Lakes Fish Contaminants Quality Assurance Project Plan,* and *The Great Lakes Fish Monitoring Program Quality Management Plan* (Appendix 1).
Provision of quality training	The GLFMP Program Officer is trained on the USEPA quality system requirements by the GLNPO Quality Team and has access to available quality implementation tools and reference and guidance documents. GLFMP grantees that are performing the laboratory analyses are required to submit a QAPP outlining their quality procedures, and to participate with the GLNPO Quality Team during periodic audits to ensure that quality procedures are being followed. GLFMP partners involved in fish collection and processing are required to follow the *Quality Assurance Project Plan for Sample Activities* (Appendix 1), are involved in bimonthly steering committee meetings where quality issues are addressed, and are reminded about proper collection procedures through a memo released to them each fall before collection begins. GLNPO's Quality Team may conduct periodic site "visits" during the fall collection to ensure adherence to quality procedures.

1.3 Program Description

Historical: The U.S. Fish and Wildlife Service, Great Lakes Fishery Laboratory (currently the U.S. Geological Survey-Great Lakes Science Center) began monitoring fish in the mid-1960s to measure the contaminant levels of various organic substances in the Great Lakes Ecosystem. In the late 1970s, the U.S. Fish and Wildlife Service (USFWS) collaborated with the U.S. Environmental Protection Agency, Great Lakes National Program Office (USEPA/GLNPO), to monitor top predator fish in the Great Lakes. A partnership was formed, with USFWS collecting and processing the fish, and USEPA funding the analyses. The program initially measured PCBs, DDT and dieldrin. Chlordane was added in 1977.

In the 1980s, the Great Lakes Fish Monitoring Program (GLFMP) was expanded to include sport fish (coho and chinook salmon). The Great Lakes States and the U.S. Food and Drug Administration (USFDA) became additional partners, with the States collecting sport fish and

the USFDA processing and analyzing the samples for toxic chemicals. The GLFMP has evolved over time, with the number of lakes, sampling locations, species, and contaminants expanding as resources allowed and scientific knowledge demanded.

Historically, the GLFMP included 3 distinct Elements, with a fourth Element that never evolved past the planning stage. The four Elements are described below.

1) Open Lakes Trend Monitoring

The original intent of this Element was to collect relatively frequent information on long-lived, wide-ranging varieties of fish. USFWS and USEPA formed a partnership to monitor contaminants in top predator fish in all five Great Lakes. This was the first Element of the program to establish and focus on lake trout and walleye as top predator fish. The collection of smelt – foragers intermediate in the food chain – was added to the collection scheme in 1989. One site in Lake St. Clair was also added in 1989. Chemical analysis for this Element was conducted by USGS through 1998. Collection of smelt for this Element was dropped shortly after it began due to lack of funding.

Because this part of the program was designed to assess the overall effects of toxic chemicals on fish, whole fish are used for monitoring, including parts not routinely eaten by humans such as liver and bones. The pollutants being measured meet three standards:

- continuity of testing, that is, the pollutants tested in the past were to be tested in the future;
- the specific analysis techniques needed to be comparable to those used in the past, to preserve continuity;
- the specific pollutants (and their precursor or breakdown products) needed to be known or expected to be found in the open lakes.

Original objectives of Element 1 include:

- Provide an indication of environmental quality.
- Identify contaminant levels in fish and their trends.
- Assess the impact of regulatory controls on whole lake conditions.
- Provide an early warning for new contaminants.
- Identify potential harm to fish stocks.
- Identify transboundary contamination.

2) Sport Fish Fillet Monitoring

This Element was added to the program in the early 1980s to directly link the condition of the Great Lakes to the health of it users. For this Element of the program, each Great Lakes State collected 15 fillets from coho or chinook salmon (or rainbow trout, if neither is available) at each designated site and provided them to GLNPO to be incorporated into the GLFMP. The U. S. Food and Drug Administration originally performed the chemical analysis for this Element through a cooperative agreement with EPA. In 1997, U.S FDA discontinued the cooperative agreement and GLNPO began to pay for analyses for this Element in addition to Element 1.

Original objectives for this Element include:

- Identify potential human health concerns
- Provide support data for States advisory programs
- Provide a basin-wide picture of fish contaminants in each lake, using fish of a single age
- Monitor new contaminants
- Improve cooperation among state agencies

3) Emerging Problems in Harbors and Tributaries

This Element of the GLFMP involved the cooperation between the Great Lakes States and EPA/GLNPO to collect and test whole fish (especially species that do not incorporate a large area) from major harbors and tributaries.

The objectives included finding emerging chemicals before they affected an entire lake, and identifying source areas of compounds already causing pollution problems in a lake. States collected the samples and GLNPO provided the analyses and published the results. Lack of funding caused this Element to be eliminated from the GLFMP.

4) Fish Tumor and Ecosystem Health Monitoring

Fish tumor monitoring was intended to be added to the GLFMP following a noticeable increase in the incidence of grotesquely deforming tumors in common fish, such as catfish or bullheads. The Great Lakes Water Quality Agreement began to focus more on overall ecosystem health in the late 1980's. The presence of tumors is a powerful indicator of negative ecosystem health. GLNPO scientists were working with other groups to design a fish tumor monitoring program with the following objectives:

- guage the incidence of tumors;
- help identify causes of tumors;
- develop a standardized tumor reporting system and centralized database; and
- determine the feasibility of using biochemical and physiological tests to evaluate contaminant effects on fisheries

This Element was never implemented into the GLFMP due to funding limitations.

Current: The Open Lakes Trend Monitoring Program and the Sport Fish Fillet Monitoring Program make up the present day Great Lakes Fish Monitoring Program. The GLFMP utilizes Quality Assurance Project Plans for sample collection, preparation, and analysis to document the type and quality of data needed for environmental decisions and to describe the methods for collecting and assessing those data. Because the GLFMP is a continuing program, aspects of the GLFMP are not static and evolve over time. As changes are made to the Program, they are documented in the appropriate QAPP.

Open Lakes Trend Monitoring

This Element of the GLFMP has continued through time with relatively few changes. Beginning in 1999, the GLFMP began to conduct sample collections, sample prep, and chemical analysis of samples through a variety of contracts, cooperative agreements, or assistance agreements (Appendix 1). Detailed collection and site information is located in the Quality Assurance Project Plan for Sample Collection Activities (Appendix 1).

Sport Fish Fillet Monitoring

This Element of the GLFMP has been more subject to change over time. Namely, collection for Element 2 has become more standardized over time as documented in the Quality Assurance Project Plan for Sample Collection Activities (Appendix 1).

1.3.1 Mission

Historical: During the late 1960's and early 1970's, the Great Lakes Community became aware of the widespread toxic contamination in the Great Lakes. Following the joint U.S. and Canadian Great Lakes Water Quality Agreements of 1972 and 1978, the International Joint Commission (IJC) helped develop and plan a coordinated surveillance and monitoring program. The overall goals of the program included:

- the ability to assess compliance with pollution control requirements and achievement of objectives;
- the collection of data necessary for measuring loads and whole lake response to control measures; and
- the identification of emerging problems.

The GLFMP was established as an important part of this program.

By the mid-1970s the Great Lakes scientific community recognized that aquatic biota such as fish were excellent integrators of aquatic ecosystems and thus could be used as indicators of overall ecosystem health. The usefulness of direct water quality measurements were limited by both spatial and temporal restraints, as well as method detection limits for many of the contaminants. Fish were considered prime candidates for use in monitoring contaminant trends because of their high profile to the public and their relation to human health, their ability to bioconcentrate and integrate certain chemicals, their position at the top of aquatic food chains, and their own sensitivity to other stressors placed on the ecosystem by humans. The main limitation of using fish as biomonitors is that fish do move around to various degrees, thus making interpretation of the data difficult without adequate information about population dynamics and migration patterns.

Current: The ultimate mission of the Great Lakes Fish Monitoring Program is to support GLNPO's goal to restore chemical integrity to the Great Lakes Ecosystem by reducing toxic substances, with an emphasis on persistent bioaccumulative toxic (PBTs) substances, so that all organisms are protected. Over time, these substances will be virtually eliminated.

The GLFMP, in cooperation with various States, Federal Agencies, Tribes, and other key partners has monitored contaminants in Great Lakes Fish since 1978. Element 1 of the program

is designed to provide indicators of the health of the Great Lakes ecosystem through the measurement of contaminant trends in whole lake trout (walleye in Lake Erie) in each of the lakes. Element 2 of the program is designed as a way to measure human exposure to pollutants through analysis of coho and chinook salmon fillets (rainbow trout fillets in Lake Erie). As a planning and assessment tool, the GLFMP measures the overall success of bans, restrictions and other remedial actions to control lake pollution. It has also provided information on new toxic compounds entering the lakes' ecosystem. These objectives are accomplished by a systematic program of harvesting and analyzing fish to ascertain the level of toxic pollutants in fish tissue.

1.3.1.1 Accomplishing the Mission

Historical: The GLFMP was originally designed in the late 1970's to provide indicators of the health of the Great Lakes Ecosystem. At its inception, sampling and analyses for the GLFMP was conducted by numerous state and federal agencies, coordinated by the Great Lakes National Program Office, and results were peer-reviewed, reported to public authorities, and published in scientific journals.

The original design of this component specified the monitoring of contaminant trends in the open waters of the Great Lakes (using fish as biomonitors), and assessing the overall effects of toxics on fish and fish consuming wildlife. These whole fish include parts that humans do not eat, but that wildlife do consume. Thus the program that was initially designed in the late 1970's was perfect for answering the bigger ecosystem health question, but was difficult to relate directly to human health. In general, an improvement in ecosystem health is representative of improving human health. However, data collected for Element 1 of the GLFMP has never been used to directly assess human health and has not been used in fish consumption advisories.

The program design designated the collection and analyses of lake trout (walleye in Lake Erie) from each of the Great Lakes in the fall of the year, using fish of similar size to reduce the impact of size variation on contaminant trend data. Size is used as a surrogate for age, 600 – 700 mm lake trout assumed to be between 7 and 8 years old and 400 – 500 mm walleye are assumed to be between 4 – 6 years old. Fish samples were then analyzed for several different contaminants, including PCBs, toxaphene, chlordanes, nonachlors, and other organochlorine compounds.

In the 1980's Element 2 of the GLFMP was added in an attempt to address human health issues more directly. The majority of the data collected for this Element is not robust enough to detect any significant trend. The inclusion of sport fish in this program, however, does provide a snapshot of contaminant concentrations across the Great Lakes in fish of consistent age, complementing the size-based data collected in the open lakes component. The program provides for the collection of skin-on fillets from coho or chinook salmon (or rainbow trout, if neither is available) by the Great Lakes States. Fish samples are then analyzed for several different contaminants, including PCBs, toxaphene, chlordanes, nonachlors, and other organochlorine compounds. The States and Tribes have used this data to augment their fish advisories and the GLFMP has used the data to make general assessments of human health. Using the standardized sampling and analyses techniques developed by the GLFMP, the States and Tribes were able to improve the reliability and comparability of their internal data, raise public confidence in the results and promote uniform and consistent health advisories.

Standardized monitoring methods also helped to produce commonly accepted measures of objectives and program performance for state and local groups participating in the Great Lakes Water Quality Agreement.

The GLFMP has also played a crucial role in the identification of newer or "emerging" contaminants in the Great Lakes prior to becoming widespread and toxic in the environment. This part of the program was initially addressed by Element 3, Emerging Problems in Harbors and Tributaries. Following the discontinuation of this Element, emerging contaminants have been addressed using fish collected for Elements 1 and 2. The 1998, GLFMP Request for Proposals (RFP) for Elements 1 and 2, included an emerging contaminants component. The Principal Investigator (PI) awarded the grant for 1999 – 2003, took the most contaminated composite of each species from the lower three Great Lakes (Michigan, Erie, Ontario) from each year and examined the extracts for all halogenated compounds that could be detected, and identified them. Historically, the contaminants of concern have been found in higher concentrations in the lower lakes and so it seems more likely to find emerging contaminants in these samples.

In addition, full scans for a variety of contaminants were conducted by the GLFMP PI and EPA/GLNPO following the Workshop on Identifying Emerging Contaminants for Fish Contaminant Monitoring Programs (Appendix 2) in the spring of 2001. It was well known at the time that several emerging contaminants were being found throughout the environment, and the GLFMP brought in five experts to present their most recent research on the presence and prevalence of emerging contaminants. The goals of the workshop were to 1) provide scientific input to EPA and the states on what contaminants of present or emerging concern should be included in the GLFMP and 2) provide scientific guidance on how to identify or anticipate potential contaminants of concern in fish tissue in the future. The overall purpose of the workshop was to provide a mechanism for improving and updating the list of contaminants currently considered in the GLFMP. Following the Workshop, several "new" chemicals were added to the routine monitoring list, and several others were chosen to be measured qualitatively in a few of the most contaminated composites.

Current: Many partner agencies continue to participate in pieces of the GLFMP. However, following the withdrawal of USGS-BRD from the cooperative agreement with GLNPO, GLNPO has taken on a much larger role in the management of the GLFMP. Because the GLFMP assesses both ecosystem health and human health over time, it is crucial that the data be comparable from one year to the next. Strict quality control procedures are in place and will be discussed further in Section 2 of this QMP.

In 2005, a new RFP was issued, describing a slightly different approach to the analyses of emerging contaminants. The GLFMP grant was issued for five years and the PI is expected to conduct one Extended Program year over the course of five years, to look for specified emerging contaminants, as decided by the steering committee. Of the emerging contaminants added to the routine monitoring list following the 2001 conference, only PBDE's, mercury and PCDD/F's will continue to be analyzed along with the routine samples.

The GLFMP has evolved greatly over the course of its existence and its flexibility is one of the many factors that has allowed it to stay relevant for such a long period of time. The continued success of the program is based on the overall structure and organization of the Great Lakes

National Program Office. This includes its communication network and working relationships with the eight Great Lakes states and the participating Tribal Nations. Cooperation among the States and tribes, including access to a database of geographically and historically dispersed information on pollution trends, and the application of sound scientific procedures to critical public policy questions also contribute to the success of the GLFMP.

1.3.1.2 Setting Goals to Accomplish the Mission

The Great Lakes Fish Monitoring Program Program Officer meets with the Monitoring, Indicators and Reporting Branch Chief at a minimum of twice a year during performance evaluations to review and assess progress, identify goals for the coming year and outline technical activities to meet those goals. These activities typically include:

- Coordination between GLFMP partners
- Review and assessment of data collected
- Development of environmental indicators
- Development of reports/publications
- Participation in conferences, sometimes as invited speaker
- Binational coordination
- Program Officer management of GLFMP grantee
- Website maintenance of GLFMO information
- Insuring that GLFMP meets quality guidelines

Additional activities may include:

- Development and release of Request for Proposals (RFP)
- Organization of proposal reviews
- Development of program QAPPs and QMPs
- Organization of program peer review
- Review of program QAPPs
- Quality system visits/audits

Section 2
Quality System Components

The GLFMP must implement a quality management program that provides the management and technical practices to ensure that environmental information collected and used to support Agency decisions are of adequate quality and usability for their intended purpose. The GLFMP uses a wide variety of quality management practices and tools to implement its quality system including:

- GLFMP quality management plan
- Project quality objectives and systematic planning
- QAPPs
- Standard operating procedures
- Training
- Steering Committee Meetings, including GLNPO management, GLFMP Program officer, PI, state representatives, tribal representatives
- Periodic meetings with GLNPO quality manager and MIRB Chief
- Quality System Audits or site "visits"
- Monthly Conference call between PI, GLFMP Program Officer and GLNPO QA staff, and contractor.

2.1 GLFMP Quality Management Plans

This QMP serves to document the GLFMP's quality system and also to communicate the quality system to all GLFMP partners. The QMP is developed for use by the GLFMP Program Officer and staff involved with the GLFMP from other agencies or organizations. Ultimately this QMP assures all users of GLFMP data that they are of high quality and can be used for environmental decision making. This QMP is approved by a GLNPO Quality Staff representative and the GLFMP Manager.

2.2 Systematic Planning and Project Quality Objectives

2.2.1 Systematic Planning

Historical: The GLFMP was created as a result of the coordinate surveillance and monitoring program planned by the IJC (see section 1). According to the paper, Contaminants Surveillance Program for the Great Lakes, Rational and Design, there were several specific objective of the Contaminants Surveillance Program:

- to provide baseline information on contaminant residue levels in Great Lakes fish and other biota
- to provide information regarding trends of contaminant residue levels in Great Lakes fish and other biota
- to locate and identify specific sources of contaminants
- to relate trends in contaminant concentrations to remedial action programs

- to determine from trend analysis when to re-open fisheries that were closed because of excessive residues in fish and to warn of the possible occurrence of intolerable residues in fish stocks
- to determine the effects of residues on fish and other biota through(a) association with the results of laboratory and field toxicological studies, and (b) observations on spawning success, recruitment in lake populations, etc.
- to evaluate the pollution potential of materials which are not now considered to be "contaminants" but which enter the Great Lakes environment.

In order to achieve these objectives, the IJC wanted to include benthos, water and sediment data in its surveillance plan. However, this document focuses solely on the fish monitoring portion of the IJCs original plan.

The success or failure of the fish surveillance plan would ultimately be determined by the program design. Several factors needed to be considered, including the determination of sampling sites and species to be sampled. Because there are seasonal variations in body burdens of fish, it was determined that collections needed to be made at the same time every year. The fall was suggested as a time when there would be the greatest availability of fish and also the least likelihood of shifts in body burdens of contaminants caused by spawning, except by fall spawners. It was recommended that there be two components to the program, offshore and nearshore. The IJC recommended that at a minimum, sampling occur annually at four locations offshore in late summer and fall, until after a baseline had been established. Once enough data had been collected for a baseline, then the sampling could occur every two years. In order to address locally impacted nearshore areas or suspected impacted nearshore areas, it was recommended that these sites be monitored annually. Control sites were to be monitored annually for comparison purposes.

The selection of species to be sampled was dependent upon several different factors, including "population distribution, availability, longevity, contaminants to be monitored, representativeness, lake to lake comparison, and importance in commercial and sport fisheries" Contaminants Surveillance Program for the Great Lakes, Rationale and Design (Appendix 3). Overall, eight species were considered as strong candidates: smelt, yellow perch, walleye, carp, alewife, lake trout, whitefish and coho salmon.

In addition to sampling sites and species selection, other factors needed to be considered in the design. Contaminant analyses were expensive, and thus the goal for sample size was to find the least number of samples necessary to detect statistically annual changes in contaminant concentrations. Decreasing the variability between replicate samples was one way to increase the ability to detect change. The use of whole fish was recommended as a way to decrease both biological and analytical variance. Biological variance was less for whole fish, because while there were seasonal differences in contaminant concentrations in various fish body tissues, total body burden varied little on a seasonal basis. Analytical variance can be introduced through sample preparation, including filleting, packaging, homogenization, etc., due to human error or inconsistent technique.

At the time that the GLFMP was created, appropriate size data was limited. The original design of the program called for extensive sampling in the first year to establish a statistically reliable

sampling protocol. The most reliable data available at the time was produced by USFW, Wayne Willford. These data indicated a 10% change in contaminant residue levels was statistically significant in a sample size of 40-60 individuals or 12 composites of 10 in the 240-280 mm size range, Contaminants Surveillance Program for the Great Lakes, Rationale and Design (Appendix 3).

Number and types of contaminants to be included in the GLFMP were also considered during the creation of this program. The goal was to choose chemicals manufactured and used in the Great Lakes that had known or potential toxicological effects on human health or the fishery. The chemicals fell into two classes, organics and metals. The recommended chemicals by the IJC included DDT (and its metabolites), dieldrin, PCB, some of the polynuclear aromatic hydrocarbons (PAH), perhaps mirex in Lake Ontario, and some of the organo-chlorine pesticides. Metals included Hg, Pb, Cd, As, Cu, Zn, were also recommended to be included in the GLFMP. In addition, the IJC Contaminants Surveillance plan encouraged a biological material archive for analysis in the future, a data storage plan, and a quality assurance plan that would include inter-laboratory analytical comparisons and sampling methodology comparisons.

Following the release of the Contaminants Surveillance Program for the Great Lakes, Rationale and Design (Appendix 3), scientists from the Environmental Protection Agency, Great Lakes National Program Office and the United States Fish and Wildlife Service began to map out the objectives and design of the Great Lakes Fish Monitoring Program. The goal was to use the suggestions from the CSP plan but also to take funding limitations into consideration. Although the original plan was to have the United States and Canada establish a coordinated fish monitoring plan, the two countries instead established independent programs that used different methodologies and thus could not be directly compared. Differences in the program include individual sample vs. composite, analysis, whole body vs. dorsal plug sampling, and site selection. The Contaminants Surveillance Program document had recommended nearshore and offshore components of the program. The Canadians followed this plan by including lake trout and smelt and added other forage fish to their Great Lakes Fish Contaminant Surveillance Program and incorporating both organic contaminants and metals into their analytical work. In addition, they designed their program to use individual whole fish collected according to age in order to maintain the statistical power that results from compositing samples (Mike Whittle, Department of Fisheries and Oceans, Ontario, personal communication, 2005).

The Great Lakes Fish Monitoring Program species collection originally included lake trout (walleye in Lake Erie and Lake St. Clair) and smelt. However, smelt collection was never fully funded or implemented. Sport fish were added to the program in the early 1980s. Other changes to the program shortly after its creation included the elimination of metals analysis and the decision to collect fish according to size as an indication of age, GLFMP significant events (Appendix 4). The original design of the GLFMP called for the collection of 60 lake trout with 20 fish in the small category (300-450mm), 20 fish in the medium category (451-650 mm) and 20 in the large category (>650 mm). Both a spatial and temporal comparison of samples was to be conducted using all three size categories of fish using analysis of covariance techniques. Unfortunately, the data did not meet the requirements for the test and the original design had to be abandoned and was replaced by the use of mean statistics with specific size ranges of fish. In 1982, a final program design was adopted and has continued through the present.

Several factors played a role in the selection of lake trout for the Open Water Trend Monitoring

portion of the GLFMP. Lake trout are representative of the offshore zone in the three upper lakes, but not in Lakes Erie or Ontario due to the fact that the populations sampled are relatively local to their spawning areas. Lake trout are top predators and long lived and were considered to be excellent concentrators of contaminants. Walleye were chosen to be collected in Lake Erie because they have similar characteristics to lake trout and are available in greater abundance. Lake trout in the larger size range (>650 mm) were not available in Lake Ontario until 1982. Lake trout were collected at the Lake Ontario sites prior to 1982, and the resulting data were probably skewed lower in contaminant concentrations than they would have been if fish of the appropriate size had been available.

Current: 50 adult lake trout between 600 and 700 mm in length (50 adult walleye in Lake Erie between 400 and 500 mm in length), are collected and then composited to form 10-5 fish composite samples per site for the Open Lakes Trend Monitoring Program.

Fifteen coho or chinook (rainbow trout in Lake Erie) are collected in the small, medium, and large size range and composited to form 3 -5 fish composite samples per site for the Sport Fish Fillet Monitoring Program.

2.2.1.1 Representativeness

A limitation of the GLFMP is the fact that fish are difficult to use as indicators of environmental quality without adequate past history information. In other words, scientists don't know exactly where each fish has been. Without that information, it is difficult to describe what the sample represents. For example, are fish collected at the Saugatuck site in Lake Michigan representative of the entire lake or only the site that they were collected? Because each lake is a unique ecosystem, a discussion of each individual lake's representativeness is included.

Open Lakes Trend Monitoring Program

Lake Michigan: There are three GLFMP sites located in Lake Michigan - Saugatuck in the southeastern part of the lake, Sturgeon Bay in the northwestern part of the lake, and Charlevoix in the northeastern part of the lake. Saugatuck and Sturgeon Bay are the two main sites sampled, with only a few years of data collected for the Charlevoix site. Patrick Schmalz (Schmalz et. al., 2002) and others studied a population of lake trout in northwestern Lake Michigan to determine the distances that they would travel. Based on other lake trout movement studies that have been completed in Lake Michigan and Lake Superior, they hypothesized that lake trout would occupy an area within 80 km of the tagging location. Their results concurred with the prior studies, showing that lake trout recaptured during 1983-1997 in northwestern Lake Michigan did not travel far, but rather remained within a fairly well-defined area with a radius of approximately 68 km. The lake trout tagged in the fall did return to the same spawning reefs in successive years, but it appeared to the researchers that the lake trout occupied the same general area during the whole year, rather than demonstrate distinct movement patterns in the fall. The researchers also noticed that lake trout movement tended to be greater along the western shore than across the open waters of Lake Michigan. The lake trout in the study would only have had to travel 80 km directly east to reach the Michigan shore, however only 9 recaptures were made on the Michigan side, compared to 182 along the western shore at distances more than 80 km. This suggests that areas of open water may separate lake trout stocks in Northern Lake Michigan.

The three GLFMP sites in Lake Michigan represent three distinct populations of lake trout. Based upon their locations, it can be assumed that there is very little transfer of fish between the three sites. However, there may always be exceptions to the rule. Some factors that could cause lake trout to move further than expected could be increased adult population density, which can lead to increased dispersal radius, spawning, food and environmental conditions. Other movement is simply random. Fish collected at each GLFMP site in Lake Michigan have most likely integrated and thus are representative of an area of approximately 68 km surrounding the collection site.

Lake Superior: There are two GLFMP sites in Lake Superior – the Apostle Islands in the western half of Lake Superior on the Wisconsin side and Keweenaw Point in the eastern half of Lake Superior on the Michigan side. Steve Schram, from the Wisconsin DNR Bayfield Office, has participated in GLFMP lake trout collections from the Apostle Islands site since the early 1990s. The Wisconsin DNR has collected the fish in 25-65 feet of water off of the Gull Island Shoal during spawning in mid-October. Recaptures and tag returns from anglers have helped biologists determine that many lake trout stay within the Gull Island Refuge after spawning, while some travel east to the Keweenaw Peninsula in Michigan. Some lake trout may travel around the Peninsula into Keeweenaw Bay. Generally, the fish collected at the Apostle Islands represent the western end of Lake Superior and are not influenced by Duluth Harbor (Steve Schram, personal communication, 2005). Sean Sitar, from the Michigan DNR in Marquette, has assisted in collection of lake trout from the Keweenaw Point site in the past. Michigan DNR has suggested that lake trout in Lake Superior travel about 50 km from their home spawning area. In addition to the physical separation between the two Lake Superior sites, GLNPO may also need to take into consideration the differences between the types of fish in Lake Superior, ex. Siscowet lake trout vs. lean lake trout. The Keewenaw Point site has a large siscowet population; these fish tend to live in deeper waters while lean lake trout (collected for GLFMP) tend to inhabit more shallow waters. A concern exists that siscowets are frequently found in more shallow water and can be mistaken for lean lake trout when collected by inexperienced staff. In order to avoid this situation, Michigan DNR has suggested to GLNPO to take lateral head photographs and whole body shots to create a photographic archive to decrease variability in future collections. At a minimum, fish collectors should be trained to distinguish between the two morphologies before annual collections (Sean Sitar, personal communication).

Lake Superior lake trout are mostly wild fish and have homing instincts to return to their spawning reefs every fall. For this reason, fish are collected from the same population every year at each site and those populations are distinct from one another. Historically, before the wild lake trout populations stabilized, some hatchery fish were collected along with wild fish. Although the hatchery fish don't have the homing instincts of the wild fish, they tend to stay in the same general area where they were released so distinct populations were still most likely being collected. Because the diets of the hatchery fish and wild fish are similar - smelt, whitefish, chubs and herring – the mix of hatchery and wild lake trout most likely did not significantly affect measured contaminant concentrations. A recent publication studying the movement of lake trout in Lake Superior from 1973 to 2001 (Kapuscinski, et. al., 2005) suggests that a fair proportion of the fish do not travel long distances, but rather stay within about 42 km of the spawning reef. Some lake trout do travel further distances and may integrate more of the lake. However, based on the observations of scientists in the field and the recent Kapuscinski manuscript, it can be assumed that each site represents an area of about 50 km.

Lake Huron: There are two GLFMP sites located in Lake Huron – Rockport in the northwest part of the lake and Port Austin in the southwest part of the lake. Both sites are located on the Michigan side of Lake Huron in U.S. Territory. The Michigan side of Lake Huron is essentially divided into three separate management units and populations of lake trout (MH1 – MH3) (Johnson et. al., 2004). MH1 extends from the Straights of Mackinaw south to Rogers City (Northwest of Rockport) and is the coldest part of the lake. Lake Trout are slower growing in MH1 due to the limited nutrients associated with this area and seem to have the most lamprey wounds compared to the other two regions. MH2 is located in the Rockport area and extends from Rogers City south to the Black River Harbor (south of Thunder Bay). The GLFMP site of Rockport is included in this management area. MH3 is located in the Port Austin area and extends from River Harbor to the southern most point in the lake. The GLFMP site of Port Austin is included in this management area. There is a gradient across the management units with increasing growth rates and decreasing lamprey wounding rates from North to South. The MH1 fish do not migrate into any other management units (McClain, et. al, 1998), while the MH2 fish do sometimes migrate to the MH1 area. MH3 fish tend to migrate in a southeasterly direction (McClain et. al., 1998), although some do migrate into Saginaw Bay, which is not included in MH3 (James Johnson, Michigan Department of Natural Resources, personal communication). There is some mixing between Canadian and US lake trout in the Lake's main basin, but there is no mixing between the Georgian Bay and the North Channel and the main basin. Lake Huron has a lot of structural diversity which helps explain why the fish are separate populations and do not travel far from their management units.

Lake Erie: There are two GLFMP sites located in Lake Erie – Dunkirk in the eastern part of the lake along the New York coastline and Middle Bass Island in the western part of the state off the coast of Ohio. Lake Erie can be separated into three distinct basins, which are linked together along an east-west axis and separated by shoals and reefs. The Western Basin extends from Toledo in the United States at the western tip of the lake to Point Pelee in Ontario and is the shallowest basin with an average depth of around seven meters. The central basin extends from Point Pele to Long Point in Ontario and averages about 20 meters in depth. The eastern basin extends from Long Point to Buffalo, NY in the United States and has an average depth of about 40 meters. Lake trout are currently present in the eastern basin. However, at the time the program was designed, walleye were selected for the GLFMP due to the limited availability of lake trout.

Several tag-recapture studies have been completed over the years examining walleye movement and distribution in Lake Erie. Two of the more recent studies include NYDEC reports, "Distribution of Marked Walleye in New York Waters of Lake Erie," February 1988, Einhouse and Shepherd, and "A Preliminary Examination of Walleye Distribution and Exploitation in the Eastern Basin of Lake Erie Using Tag-Recapture Data," November 1995, Einhouse and Haas. Both of these studies suggest that the eastern walleye occupying New York waters are essentially local and do not seem to stray much from their original spawning sites. The 1995 study, however, also demonstrated that unlike the eastern walleye, the western walleye do tend to migrate large distances and thus contribute to lakewide fisheries. Large female walleyes are typically the segment of the western basin tagged walleye population that has a range extending into eastern Lake Erie. These studies also demonstrated the homing behavior of walleyes to their spawning site each spring. Although the GLFMP fish collections collect the lake trout during their fall spawning season, the walleyes are still migrating during the fall collection and do not

return home until the spring to spawn. Because of this migration, it can be assumed that some western basin walleye are collected each fall in the Dunkirk site. The Middle Bass Island collection is most likely composed of western basin walleye, some which have integrated the entire lake. These fish may also have traveled north after spawning into the Detroit River, Lake St. Clair, and into Lake Huron.

Lake Ontario: There are two GLFMP sites located in Lake Ontario along the New York coastline – North Hamlin in the central part of the lake and Oswego in eastern part of the lake. North Hamlin is located approximately equidistant from the western and eastern coasts near Rochester, NY. Oswego is located well east of North Hamlin, near the mouth of the Oswego River. There have been two main studies published regarding lake trout dispersal in Lake Ontario (Elrod, 1987, and Elrod, et al, 1996), and both have concluded that most of the lake trout remain in the same general region where they were initially stocked. According to these studies, fish stocked east of the Niagara River rarely crossed the river mouth into Canadian waters west of the river. Also, few lake trout moved across Lake Ontario between the north and south shores, or between the eastern outlet basin and the main lake basin. North Hamlin is one of the stocking sites on Lake Ontario, and both studies found that fish stocked at North Hamlin tend to disperse both east and west. Joseph Elrod (Elrod, 1987) found that the dispersal was not caused by random swimming movements, but was greatly affected by currents. North Hamlin is one of four south-shore stocking sites, and 84% of the fish stocked at those sites were found within 30 km of where they were stocked (Elrod, 1987). Although Oswego is not one of Lake Ontario's four stocking sites, it does lay between two of the south-shore sites, Sodus and Mexico Bay. Based on the 1996 study, fish stocked at North Hamlin tend to move along most of the southern shore and do not typically travel west of the Niagara River or into the eastern basin of Lake Ontario. Fish stocked near Oswego, also tend to integrate much of the southern shore of Lake Ontario. However, fish stocked at North Hamlin appear to be spending more time integrating the western side of the southern shore, while the Oswego fish appear to spend more time integrating the eastern side of the southern shore (Elrod et al, 1996). It appears that mature lake trout do have some tendencies to return to their stocking sites in preparation for fall spawning. However, this tendency appears to be weak (Elrod et al, 1996).

Sport Fish Fillet Monitoring Program

The sport fish fillet monitoring Element was added to the GLFMP in 1980, to help answer the questions regarding contaminants and human health. This Element was planned around the annual Great Lakes States' fall field collections, which were already taking place irrespective of the GLFMP. The objectives of the Element were to provide the States with some additional data for their fish consumption advisories, provide a uniform protocol to the States for sampling and analyses (allowing comparisons between States), and to provide GLNPO with a better indicator of human health in the Great Lakes. This Element was also set up as a true partnership between the Great Lakes States, GLNPO and USFDA, with virtually no exchange of funds between the three groups.

Fall run coho salmon were chosen for contaminant monitoring because of their popularity as a sport fish, their rapid growth rates as they consume large quantities of alewife and other forage fish and their migratory behavior in Lakes Superior, Michigan, Huron, and Ontario. Steelhead or Rainbow Trout were chosen in Lake Erie because of limited stocking of coho and chinook salmon. Coho move about the nearshore and open waters of the Great Lakes while maturing,

depending on water temperature and the availability of prey. For example, in Lake Michigan, Wisconsin anglers know to look for coho salmon in the spring in the southern waters of Lake Michigan in nearshore areas, where the water tends to be warmer and the alewife congregate. Then as temperatures increase, the coho tend to move north along the western coast and then during the heat of summer may move to offshore deeper waters where its cooler and where their prey is often located. Few studies have actually been done documenting migration patterns of salmon in the Great Lakes. Much of what is known is from anglers that search for the coho beginning in the spring and ending at the tributaries in the fall, where the coho return to spawn. One exception to this is in Lake Ontario, where two studies have been published documenting the movements of Pacific salmon (Haynes and Keleher, 1986, and Haynes and Gerber, 1989). These studies showed that Pacific Salmon in Lake Ontario use wide geographic and temperature ranges in the summer, and that the Pacific Salmon don't necessarily show a directional preference of moving with a current. It is because of this demonstrated migratory behavior that salmon were thought to be excellent choices for contaminant monitoring.

The program's original assumption was that salmon would be representative of overall conditions in each Lake. Despite existing studies and evidence from anglers, it is not certain that the salmon in the GLFMP are representative of each entire Lake. In addition, natural reproduction in certain tributaries confounds the issue of representativeness. Stocked coho salmon are generally released from hatcheries at about 1 year of age, while naturally spawned coho will have already spent 1.5 years in their home tributary during the egg, fry and fingerling phase of their life, where they are exposed to local contaminant conditions. In addition, the fish tend to gather around the tributary before they spawn and are caught and sampled, where again they are exposed to local conditions. David Devault (DeVault et. al., 1988) found that there was a significant difference between coho from the Sheboygan site in Lake Michigan compared to the other Lake Michigan sites. Contaminant levels in the Sheboygan fish were significantly higher than the other Lake Michigan fish, which suggested that the fish were in fact more representative of local conditions than conditions in the entire lake.

Another issue with the sport fish fillet monitoring Element is the small number of sites per Lake. Although Lake Michigan has many collection sites, the other Lakes have only one or two, and so it would be impossible to say with certainty that those few sites are representative of the entire Lake, regardless of the migration patterns of the fish. The limitations of sampling sites in the remaining lakes also prohibit the use of GLFMP sport fish data for trend analysis.

2.2.2.1 Original Project Quality Objectives

The Data Quality Objective process can be used for systematic planning and is described in EPA's document Guidance for the Data Quality Objective Process, EPA QA/G-4, August 2000 (G:\ALL\QA\GLNPO QMP). Generally, data quality objectives (DQOs) are statements of the overall maximum uncertainty associated with the measurement system and the population that the data users are willing to accept in the results derived from data collection activities. Essentially, the DQO design is intended to answer the primary question of theprogram. It is the responsibility of the GLNPO PO to define this allowable uncertainty and develop DQOs with the principal investigators and cooperators.

Open Lakes Trend Monitoring Program

The Great Lakes National Program Office entered into a cooperative agreement with the U.S. Fish and Wildlife Service and the National Fisheries Research Center – Great Lakes (now USGS-GLSC) in 1977, Cooperative Agreement on Great Lakes Fish Contaminant Monitoring (Appendix 3). This cooperative program built upon an existing USFWS Lake Michigan lake trout monitoring program originating in the late 1960's. This existing USFWS program was used to estimate the appropriate sample size and any resulting uncertainties from collection. The original sampling design stated that a 10% change in contaminant residue levels was statistically significant in a sample size of 40-60 individuals or 12 composites of 10 in the 240-280 mm size range Contaminants Surveillance Program for the Great Lakes, Rationale and Design (Appendix 3). The original design of the GLFMP attempted to balance the USFW's sampling design with a limited budget. The resulting goal of the GLFMP became the ability to detect a 20% change from current contaminant levels by analysis of variance where alpha = .05 and beta = .20 with a minimum collection of 20 fish within a specified size range. The GLFMP's collection scheme called for the collection of 60 lake trout (or walleye) per site each year in 3 size categories, small (300-450 mm), medium (451-650 mm), and large (>650 mm), with 20 fish in each category. To reduce analytical costs, the fish were grouped into four composite samples consisting of five fish each within each size category. According to Dave Devault (DeVault et. al., 1986), the original GLNPO coordinator of the GLFMP, the program was initially designed to compare contaminant levels in fish, both temporally and spatially, in the three size categories collected from each site through analysis of covariance.

The original sampling design of the GLFMP was adhered to following the creation of the cooperative agreement. However, the design was not sufficient to meet the program's goal of a 20% detectable change in contaminant concentration between consecutive sampling periods at each site within the 95% confidence interval. In 1979, the analytical and collection designs of the program were revised to use mean statistics for specific size ranges of fish to compare contaminant concentrations between sites and within sites over time.

Sport Fish Fillet Monitoring Program

The GLFMP Sport Fish Fillet Monitoring Element was not designed to meet a specific data quality objective. Rather, it was designed to take advantage of existing State run fish consumption advice monitoring programs. In 1980, a partnership was formed between G LNPO, the 8 Great Lakes States, and the USFDA to analyze sport fish for contaminants to identify human health data. The States volunteered to collect sport fish for the GLFMP, in addition to their own collections, and provide them to GLNPO. The USFDA volunteered to analyze these data, along with their own samples, and provide the results to both the States and GLNPO. Objectives of this program includeddetermining the potential for human exposure to contaminants, providing a consistent basin wide database, providing the States with fish contaminant data to augment their advisories, and improving the cooperation among state agencies in issuing advice.

An attempt was made to identify trends in sport fish fillets at the start of the Sport Fish Monitoring Program. Lake trout fillets were to be collected in conjunction with the Open Lake Trend Monitoring Element. The USFWS would collect fillets from the largest size class of lake trout or walleye at one open lake station on each of the Great Lakes. USFDA would perform the analyses. Residue levels in the lake trout fillets were thought to represent the maximum

exposure levels for Great Lakes fish consumers. The measurement of contaminants in lake trout fillets would allow for the relationship between whole fish contaminant levels and fillet contaminant levels to be explored. Although the lake trout fillets were included in the GLFMP plan in the early 1980's, this part of the program was only implemented in 1980, 1982 and 1983.

Deviations from GLFMP Standard Operating Procedures

Sample Size – The original sampling design for the GLFMP Open Lake Trend Monitoring Program called for the collection of walleye from Lake Erie in the 400 – 500 mm size range, (DeVault et al 1996). However, according to the USGS QAPP for sample collection, Quality Assurance Project Plan for EPA / IAG Title: Monitoring Trends of Selected PCB Congeners and Pesticides in Fish from the Great Lakes, 1991, 1992, and 1993 (Appendix 2), the range for walleye collection was between 450 and 550 mm. The U.S. Geological Survey, Great Lakes Science Center was responsible for fish collections for the GLFMP from 1977 through 2003 and performed chemical analysis for the program in the early and mid 1990's. Historical data shows that the mean walleye length falls below the 450-550 mm size range in the years 1977, 1978, 1979, 1980, 1981 and 1982 and that the mean length values have never been above 500 mm. Thus the data supports a walleye size range of 400-500 mm as documented by DeVault in his 1996 manuscript. However, mean walleye length does range between 450 – 550 mm for 2003 and 2004 fish and returns to the 400 – 500 mm mean length in the following years. This deviation occurred following the introduction of a new program officer to the GLFMP (Elizabeth Murphy) in 2003, the dissolution of the USGS – GLSC cooperative agreement with EPA, and the incorrect quality documentation in the USGS QAPP.

Analytical Methods – Prior to the creation of the GLFMP through a cooperative agreement with U.S. Fish and Wildlife Service, Great Lakes Fishery Laboratory (currently USGS-GLSC), and GLNPO, USFW was collecting and analyzing Lake Michigan lake trout for their own program (1960 – 1976). These data (1972 – 1976) are included in the GLFMP long-term trend for Lake Michigan. It is important to note, however, that the methods were different for these five years of analysis and that individual whole fish between 500-700 mm total length were analyzed instead of composites (Willford et al., 1976).

2.2.2.2 Current Project Quality Objectives

Open Lakes Trend Monitoring Program

The Great Lakes Fish Monitoring Program (GLFMP) is a long-term trends program of exceptional value, providing documentation of changes in contaminant levels in the Great Lakes ecosystem. A data quality objective (DQO) was developed for the Open Lakes Trend Monitoring Element to help guide the program's sampling and analytical efforts, and maintain consistent monitoring, as discussed in section 2.2.2.1, and was reflective of the high and changing concentrations of contaminants in fish. The original DQO for Element one of the GLFMP stated that the program should be able to "detect a 20% change between consecutive sampling periods at each site within the 95% confidence interval."

Current concentrations of total PCBs in lake trout appear to be reaching a steady state, with tissue concentrations at or below 2mg/kg. As a steady state is approached, year to year changes

in tissue concentration become more difficult to detect because these changes are small. For example, in 1999, the mean concentration in Lake Superior lake trout from the Keewanaw Peninsula was .27 mg/kg. In order to meet the original DQO, the GLFMP would have to be able to "detect a .05 mg/kg difference between two sampling periods". This would be difficult even with the best methodology and a large sample size.

In order to address this issue, a GLFMP review (Appendix 1) was conducted in February of 2005. Great Lakes stake holders for both Elements of the GLFMP, the current principal investigator for the GLFMP, and previous and present GLFMP managers were in attendance. A recommendation to "Conduct statistical power analysis on both Element 1 and Element 2 of the GLFMP in order to revise and/or develop Data Quality Objectives (DQO)" was presented to GLNPO management. In order to address the recommendation of the program review panel, GLNPO has revised its DQO for Element 1 of the GLFMP to be a detection of trends in concentration of 0.1 mg/kg/year at the 95% confidence level based on three consecutive sampling periods (6 years, as sites are sampled every other year) for a specific site (Saugatuck, Apostle Islands, etc.) with a power of 80% or greater. (Great Lakes Fish Monitoring Program Data Quality Objective Revision report – 2005, Appendix 2)

Sport Fish Fillet Monitoring Program

A DQO for the Sport Fish Fillet Monitoring Program was never created because the original objective of the program was to share data with the Great Lakes States to supplement fish consumption advice and not to analyze for temporal trends. At the GLFMP review, the Great Lakes States suggested that they were interested in addressing trends over time with this Element as well as the detection of emerging contaminants. GLNPO has also identified specific needs for a human health indicator that are currently not being met by this Element. Routine peer reviews of the program will address these issues over time.

2.3 Quality System Documentation

EPA quality policy requires every data collection activity to have written and approved quality system documentation (e.g., QAPPs) prior to the start of the collection.

Historical:

Open Water Trend Monitoring

The GLFMP began as a partnership between several different agencies and each agency was expected to follow its own QAPP and quality procedures. Cooperative agreements were used in lieu of quality documentation to identify expectations of partners when GLFMP agencies participated on a voluntary basis. The Cooperative Agreement on Great Lakes Fish Contaminant Monitoring (Appendix 3) between the U.S. Environmental Protection Agency, Great Lakes National Program Office and the National Biological Service, Great Lakes Science Center (currently USGS, GLSC) addressed operational guidelines, roles and responsibilities, and quality control issues of the Open Lake Trend Monitoring Element. Both GLNPO and USGS-GLSC recognized the importance of quality assurance in long term trend monitoring projects in the cooperative agreement.

Sport Fish Fillet Monitoring

Cooperative agreements were also established with all eight Great Lakes States, outlining their participation in the GLFMP. Each agreement used similar language and outlined standard operating procedures for sport fish collection including species, location, and time of year. Sport fish were to be collected in the fall of the year, as they began their spawning runs.

USFDA conducted analysis for the Sport Fish Fillet Monitoring Element of the program on a voluntary basis until 1997 and followed quality assurance procedures as outlined in the FDA Comprehensive Residue Analysis Report for EPA FDA Survey (Appendix 2). Prior to 1991, all Quality Assurance issues were the responsibility of the Region 5 Central Regional Laboratory and QAPPs were submitted to their office.

In 1998, both Elements of the GLFMP were included in the same funding vehicle and the University of Minnesota was granted the analytical work following the submission and approval of a QAPP, (Appendix 2).

Current: GLNPO took over Quality Assurance responsibilities in 1992 and have maintained quality documentation since that date. Clarkson University was awarded chemical analysis of the GLFMP in 2006 following submission and approval of quality documentation (Appendix 1).

In 2003, USEPA/GLNPO implemented the GLFMO Quality Assurance Project Plan for Sample Collection Activities (Appendix 1), which describes the quality assurance (QA) and quality control (QC) activities and procedures associated with collecting samples of fish tissue for the GLFMP. All States and other fish collection agencies are required to follow this QAPP when participating in fish collection procedures for the GLFMP. Any deviations from documented fish collections procedures are documented by the GLFMP Program Officer.

2.4 Standard Operating Procedures

Good laboratory practices and good management of field sampling operations include the development and use of standard operating procedures (SOPs) for all routinely used sampling, preparation and analytical laboratory methods. SOPs facilitate comparability of data generated at different times, or by different field or laboratory staff. These protocols should be detailed enough so that someone else can reproduce results using the SOP (i.e., a journal article is usually not sufficient). Methods can be included in the quality system documentation either in the body of the document or as an appendix. If the referenced method is not followed precisely, addendums to the method must be included in the documentation that clearly identifies changes to the method, such that changes are obvious to any individual using the method. If an altered method is used for an extended period of time, the full method must be revised. A method cannot be revised during project implementation without the prior consent of the PO. If the modification is accepted, it must be documented in a letter to the PO and included in the next submitted report. It is the responsibility of the PO to inform all relevant project participants of the protocol change.

Open Lake Trend Monitoring

Historical: Lake trout or walleye collections were organized by U.S. Fish and Wildlife Service (currently USGS/GLSC) between 1977 and 2003. GLNPO assumed the role of collection organization in 2003. The protocol for fish collection, handling, storage and homogenization is outlined in the Cooperative Agreement on Great Lakes Fish Contaminant Monitoring between the two agencies (Appendix 3). In addition to adhering to the Cooperative Agreement, the U.S. Fish and Wildlife Service was expected to follow its own QAPPs and SOPs to ensure quality control. Because GLNPO has always provided funding for analytical services for this Element, QAPP submission was required. These QAPPs included detailed SOPs which described analytical procedures.

The Great Lakes Fish Monitoring Program species collection originally included lake trout (walleye in Lake Erie and Lake St. Clair) and smelt. However, smelt collection was never fully funded or implemented. Sport fish were added to the program in the early 1980s. Other changes to the program shortly after its creation included the elimination of metals analysis and the decision to collect fish according to size as an indication of age, significant events (Appendix 4). The original design of the GLFMP called for the collection of 60 lake trout with 20 fish in the small category (300-450mm), 20 fish in the medium category (451-650 mm) and 20 in the large category (>650 mm). Both a spatial and temporal comparison of samples was to be conducted using all three size categories of fish using analysis of covariance techniques. Unfortunately, the data did not meet the requirements for the test and the original design had to be abandoned and was replaced by the use of mean statistics with specific size ranges of fish. The new sampling design called for a collection of 50 lake trout per site per year to be grouped into 10 five fish composites between 600 -700 mm (400 – 500 mm for walleye in Lake Erie). However, this new sampling design was not fully implemented until 1982. Lake trout data collected between 1977 and 1979 were adjusted to be compatible with other time periods, walleye data were not adjusted. This adjustment required the mean length of all the fish in the medium and large composites to be calculated. When the resulting mean length was below 630 mm or above 640 mm, the composite sample with the smallest or largest mean was dropped and then the mean was recalculated. This process continued until they reached a mean length between 620 mm and 640 mm. The selected composite samples were then treated as environmental replicates. The walleye data were not adjusted, De Vault et al., 1986.

Fish were to be weighed, measured, ground, homogenized and composited into samples by the GLSC. Then an aliquot of each sample was to be supplied to GLNPO for analyses. Specifically, three 80 g tissue samples and one bulk archive sample were to be prepared. One 80 g sample was to be sent to GLNPO or GLNPO's authorized designee, for analyses while the additional 80 g samples and the bulk archive sample was held at the GLSC as back up/archive samples. These would be analyzed in case of loss of the original samples, or as part of mutually agreed upon projects. As stated clearly in the agreement, "No archive/backup sample will be analyzed or destroyed without the prior written approval of the representatives of both agencies."

The agreement also outlined the uses of "check" samples for quality control purposes. The "check" samples were to be prepared and maintained by the GLSC and furnished to the GLNPO contract or grant laboratory (grantee) along with the other analytical samples. "Check" samples were composed of a large number of lake trout composited into a single large homogenate for use by GLNPO and the GLSC. The check samples were to be analyzed by USGS-GLSC and/ or GLNPO's grantee along with routine samples for continuity. Agreements within (+/-) 20% of

the check sample running mean for each contaminant present in environmental samples above IJC objectives outlined in the Contaminants Surveillance Program for the Great Lakes, Rational and Design (Appendix 3) were required before data were accepted. Those contaminants below IJC objectives had to agree within (+/-) 40%t. In addition, duplicates analyzed by GLNPO and GLSC had to agree to within (=/-) 25%. And finally, both GLNPO and GLSC internal quality control programs were to be reviewed and were to be included in the methodology description of the program. Additional quality control measures to "guarantee the comparability of data over time and across laboratories" are discussed in DeVault et al 1996. New "check" samples were created as needed and as older "check" samples were depleted. The most recent "check" standard is to be created by the Wisconsin Lab of Hygine in 2007 using extra fish collected from Lake Michigan, Saugatuck site, in 2004.

In addition to "check" samples, each batch of ten environmental samples was accompanied through the analytical process by check samples. When these check samples varied by more than 30% from the running mean for any chemical parameter, corrective steps including re-analysis were employed until the result met the parameters. When it was necessary to change the check samples, a minimum of 20 samples of the new check were analyzed to establish mean concentrations. The old check sample was used to ensure reliability of the numbers for the new check sample. Each laboratory performing the analyses was required to adhere to these quality control procedures, although sometimes there may have been slight modifications. For example, Dr. Deborah Swackhamer, who performed the analyses from 1999-2003, began by analyzing the check sample 10 times prior to start of the project, to establish its estimated "true" value and to be able to compare it with previous studies to ensure comparability over time. Check samples were then included with at least every 3 sample sets resulting in a minimum of 10 check samples per year. If these check samples varied by more than 35% of the running mean, all extractions halted and the procedures were checked by running duplicate laboratory spikes. Once acceptable laboratory spike recoveries were obtained, the check sample was then re-analyzed until the results fell within the acceptable criteria.

Sport Fish Fillet Monitoring

Historical: The original sampling design of this program called for the collection of 15 sport fish from a variety of sites on each lake. Coho salmon were to be collected in even years and chinook salmon were to be collected in odd years. Rainbow trout were collected when salmon were not available. Because the data for this program were to be used to identify human health information, skin-on fillets were collected instead of whole fish. In addition, data created from this program would be used to augment State fish consumption advisory programs. For this reason, size categories (small, medium, and large) were identified for the collection instead of a strict length range. State advice is issued based on size category; ex. larger fish contain more contaminants than smaller fish. Fifteen fish were collected at each site and then grouped into the three size categories. Each size category consisted of 5 fish to create 1 composite sample. Because of the voluntary nature of the program and the limited number of collection sites in some lakes, this portion of the GLFMP is not able to identify trends in sport fish contamination.

The collections of coho and chinook salmon (rainbow trout in Lake Erie) were voluntarily conducted by the Great Lakes States and Tribes participating in the program between 1980 and 1997. GLNPO began funding these collections in 1998. In order to ensure uniformity among the voluntarily collected samples, each agency was instructed to follow the USFDA filleting

procedure as documented in the FDA Comprehensive Residue Analysis Report for EPA FDA Survey (Appendix 2).

Sport fish were to be collected in the fall of the year, as they began their spawning runs. Standard skin-on- fillets were to be taken from 15 fish and composited as 3 samples from five fish each in three size categories. The fillets were to be foil wrapped and shipped frozen to the USFDA. The method for taking the standard fillet conformed to the USFDA filleting procedure in the Comprehensive Residue Analysis Report for EPA FDA Survey (Appendix 2) and was comprised of several steps:

a) Make a shallow cut through the skin (on either side of the dorsal fin) from base of the head to the tail.
b) Make a cut behind the entire length of the gill cover cutting through skin and flesh to the bone.
c) Make a cut along the belly from the base of the pectoral fin to the tail.
d) Remove the fillet and remove major bones.

The collection agencies were then instructed to freeze the fish and ship them to the USFDA laboratory in Minneapolis, Minnesota for analysis.

The analysis of the sport fish was performed by USFDA in Minneapolis, Minnesota, at no charge to GLNPO until 1997. The USFDA had its own SOPs in place for homogenization and chemical analyses, which can be found in the Comprehensive Residue Analysis Report for EPA FDA Survey (Appendix 2). In 1998, GLNPO incorporated the funding of analysis for sport fish into a cooperative agreement with USGS/GLSC to analyze whole fish. Sport fish analysis became subject to USGS's existing QAPPs and SOPs.

Current: Following the withdrawal of USGS/GLSC from the GLFMP partnership, GLNPO assumed the management of the fish collection and homogenization for both the open lakes trend monitoring and Sport Fish Fillet Monitoring Programs. The Great Lakes States and Tribes continue to collect sport fish with assistance from GLNPO for materials and shipping costs. To ensure consistency and quality control with collection and processing of GLFMP samples, the GLNPO drafted the GLFMP Quality Assurance Project Plan for Sample Collection Activities (Appendix 1). This QAPP includes SOPs for both fish collection and fish homogenization.

In addition to QMPs, QAPPs and SOPs, laboratories working with GLNPO should have a Good Laboratory Practices (GLP) document that is available for review during technical audits. These documents refer to the general practices that relate to the majority of measurements such as: facility and equipment maintenance, record keeping, chain-of-custody, reagent control, glassware cleaning, and general safety.

2.5 Training

Laboratory Analysis – *Historical*: Originally, the GLFMP relied on its partners to ensure that its employees were properly trained. However, following the withdrawal of USGS/GLSC from the GLFMP partnership, QAPPs, including documentation of the training and experience of its scientists, were required.

Current: Presently, analytical laboratories must demonstrate their ability to conduct high quality work and ensure the proper training of staff prior to receiving any analytical samples through submission of QAPPs, analysis of PE samples, and periodic visits from GLNPO QA staff.

Field Collections & Homogenization – *Historical:* Originally, field collection crews and homogenization lab staff followed the protocols in the Cooperative Agreement on Great Lakes Fish Contaminant Monitoring (Appendix 3).

Current: The training for field collection crews and homogenization lab staff is described in the Quality Assurance Project Plan for Sample Collection Activities (Appendix 1). This QAPP is distributed to all collection teams prior to collection activities. Each field sampling team is required to have the experience and knowledge to perform all field activities. The GLFMP Program officer contacts all sampling personnel annually prior to collection to review appropriate collection procedures and to answer any potential questions. Laboratories performing the homogenization and archiving of samples must also demonstrate to the Program officer appropriate levels of expertise before receiving the samples through submission of a QAPP.

2.6 Steering Committee Meetings, including GLNPO management, GLFMP Program officer, PI, State representatives, tribal representatives

The GLFMP Steering Committee was created through a recommendation from the GLFMP Program Review conducted February 7 and 8, 2005. The GLFMP Steering Committee meets biannualy to discuss the progress of the grant and make any decisions regarding changes to the program. The purpose of the GLFMP Steering Committee is to include all stakeholders in the decision making process of this highly visible program and to allow input into its direction. One of the most important responsibilities of the steering committee will be to assist with meeting the objective of identifying emerging contaminants in the Great Lakes before they become a hazard for both humans and wildlife.

Current: The GLFMP RFP, issued in 2005, required potential grantees to incorporate an extend program analysis for a list of chemicals to be determined following the grant award. Clarkson University was awarded the GLFMP grant and has planned to conduct the extend year of analysis in the 4th year of analysis. The steering committee will be heavily involved with the choice of analytes for the Extended Program year of analyses. In addition to the Extended Program, broad scans may also be performed on certain fish samples to identify “new” or emerging chemicals.

2.7 Periodic meetings with GLNPO Quality Manager and Monitoring Chief

These meetings provide updates to the Monitoring Chief on the progress of the quality control reviews of GLFMP datasets and ultimately result in the planned public release of the data. Meetings occur as necessary and prior to the public release of data.

2.8 Monthly Conference call between PI, GLFMP Program Officer and GLNPO QA staff, and contractor

A monthly GLFMP conference call was established following the Program review conducted February 7 and 8, 2005. These calls are held in order to identify progress in all areas of the GLFMP, including homogenization, extraction, chemical analyses, data QA/QC and database entry. These calls allow free discussion between those involved and can help to identify problems or bottlenecks associated with the data. The GLFMP Steering Committee can be involved in decisions that are need as a result of the monthly conference calls and as determined by the GLFMP PO.

Section 3
Personnel Training and Qualifications

The success of any quality management program ultimately lies with the personnel who implement the program on a daily basis. The GLNPO Quality Manager is responsible for ensuring that the GLFMP Program Officer understands and implements the GLNPO's quality system while managing the GLFMP. The GLFMP Program Officer is required to complete the quality system training provided by GLNPO so that he or she understands and adheres to GLNPO's quality system. He or she should understand the philosophy of improving activities to provide the highest quality data in a cost-efficient manner. In addition to the GLFMP Program Officer, all partners involved in the GLFMP should adhere to the GLFMP quality system.

Current GLFMP quality documentation can be found in Appendix 1 and historic GLFMP quality documentation can be found in Appendix 2.

3.1 Quality Manager Training

The Quality Manager regularly attends national and, in some cases, international conferences and meetings on quality systems and the development of quality management materials and protocols relevant to GLNPO. The Quality Manager will participate in training courses on quality management topics, such as data quality assessment and QAPP development. This will assure that the GLFMP Program Officer receives up-to-date training on a variety of quality assurance subjects including EPA's quality policy.

3.2 GLFMP Program officer Quality System Training

The Chief of the Monitoring, Indicators and Reporting Branch is responsible for ensuring that the GLFMP Program Officer has the qualifications to do his or her job, including those related to the quality system. The Chief is responsible for discussing quality training needs with the GLFMP Program officer during the mid-year and annual personnel performance evaluations. The GLFMP Program Officer must complete the GLNPO Quality System Training for Project Officers and the Overview of GLNPO's Quality System every three years. Other training opportunities include QA Project Plan Development and Auditing and Data Verification/Validation Techniques.

3.3 GLFMP Grantee Quality System Training

The GLFMP Grantees and are required to submit an approved Quality Management Plan and/or Quality Assurance Project Plan before they begin work and. The QMP and or QAPP must be approved by both the GLFMP Program Officer and the GLNPO Quality Manager. In this plan, they must demonstrate that their staff has the necessary training and experience needed to accomplish the work.

3.4 GLFMP Voluntary Partners Quality System Training

The GLFMP Voluntary Partners must use qualified and well-trained staff to perform their

GLFMP functions. Most of these voluntary partners are fish biologists responsible for the fall fish collections and are required to adhere to the GLFMP Quality Assurance Project Plan for Collection Activity QAPP (Appendix 1). These cooperators are also welcome to participate in the GLNPO sponsored Quality System Training. A list of past and present collectors and GLFMP voluntary partners are available in Appendix 5. A table of changes in analytical methods, analytes, laboratories, and participants is also listed in Appendix 5. A summarized list of GLFMP significant events, including changes in sampling, laboratories, and methods can be found in Appendix 4.

Section 4
Procurement of Items and Services

The GLFMP must ensure that procured items and services meet EPA regulations, are delivered in a timely fashion, and are within GLNPO's specifications. The following sections describe the GLFMP's procurement procedures.

It is GLNPO policy that quality system requirements be explicitly addressed when acquiring items or services for the GLFMP. This policy applies to procurements such as contracts, as well as to cooperative agreements, partnership agreements, grants to institutions of higher education, and other non-profit organizations, Tribes, States, local governments, and interagency agreements. The following Federal regulations contain sections relating to quality management or quality systems:

- 48 CFR Part 46. Quality Assurance - http://www.access.gpo.gov/nara/cfr/waisidx_06/48cfr46_06.html

- 40 CFR Part 30. Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations - http://www.access.gpo.gov/nara/cfr/waisidx_06/40cfr30_06.html

- 40 CFR Part 31. Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments - http://www.access.gpo.gov/nara/cfr/waisidx_06/40cfr31_06.html

- 40 CFR Part 35. State and Local Assistance - http://www.access.gpo.gov/nara/cfr/waisidx_06/40cfr35_06.html

4.1 Procurement of Items

The GLFMP will utilize the services of the EPA Region 5 Purchasing Section of the Contracts and Grants Branch for its procurement of items if necessary. Typically, the GLFMP does not procure items, only services.

4.2 Procurement of Services

Contracts and assistance agreements, such as grants and interagency agreements, are used by the GLFMP to procure services (Appendix 5).

***Historically*:** Much of the work for the GLFMP was performed through partnerships and voluntary action. These partnerships were formalized through signed cooperative agreements, but no funds were exchanged. Chemical analysis for the Open Lakes Trend Monitoring Element of the GLFMP has always been funded by GLNPO. All Quality Assurance issues associated with provided services were handled by the Region 5 Central Regional Laboratory.

Current: The GLFMP PO maintains the assistance agreements for sample collection and chemical analysis of fish tissue. The GLNPO Quality Manager maintains the contract for

GLFMP QA support and homogenization activites.

4.2.1 Assistance Agreements

Sample Analysis - The GLFMP uses assistance agreements to procure services when there is mutual benefit to GLNPO and the participating group from the arrangement. The two types of assistance agreements used in the GLFMP include interagency agreements (IAGs) with other agencies and cooperative agreements with universities. These types of funding mechanisms are chosen because they allow for substantial involvement of GLNPO in the project. The GLFMP issues requests for proposals very five years, unless otherwise determined by GLNPO, and adheres to EPA's competition policy and the GLNPO QMP. Following proposal submission, the GLFMP program officer conducts a proposal review that includes both internal GLNPO and external reviewers. The GLFMP PO presents the recommendation of the review team to the Monitoring and Indicators Branch Chief for approval and the applicant is notified of the decision both electronically and via mail. The agreement is then implemented with the help of the EPA Region 5 Grants Management Branch, which must approve all agreements before they are awarded.

Sample Collection, Preparation, and Storage – The GLFMP is responsible for sample collection and preparation. USGS/GLSC has continued to archive samples at no cost to GLNPO following their withdrawal from the cooperative agreement in 2003. Many collection agencies continue to support the GLFMP through voluntary collection of samples at sites that are on their routine collection schedules and require minimal additional time and expense. Cooperative agreements have been drafted and put into place with these types of agencies (Appendix 3). The GLFMP has entered into Assistance Agreements or Interagency Agreements with collection agencies that are not able to take on the extra expense of time and / or money to collect GLFMP samples. The GLFMP does not compete these small fish collection awards. This is allowed under the EPA competition policy, which allows GLNPO to award all IAGs, and LAMP or RAP supporting grants to States and Tribes, without competition. The fish processing and archiving is now funded through the use of contracts and is discussed in section 4.2.2.

4.2.2 Contracts

A contract is used when GLNPO derives sole benefit from a particular product or service.
Historical: Prior to 1991, the GLFMP used contracts to fund the analyses of the Open Lakes Trend Monitoring Element. All Quality Assurance issues regarding the contract were the responsibility of the Region 5 Central Regional Laboratory. After 1991, the GLFMP issued assistance agreements or IAGs for the analyses of the Open Lakes Trend Monitoring and the Sport Fish Fillet Monitoring. These agreements allowed for a more collaborative process and resulted in benefits for both parties.

Current: Since 2003, the GLFMP has used a combination of IAGs, cooperative agreements and amendments to pre-existing grants to fund fish collections and fish processing, and is currently being funded through a contract with the Office of Water to Computer Science Corporation (CSC). Fish analysis is funded through an assistance agreement with Clarkson University and the USGS/GLSC provides fish archival through a voluntary agreement.

The GLFMP adheres to EPA policy regarding competitive bidding, EPPA Acquisition Regulations (EPAAR), http://www.epa.gov/oam/ptod/epaar.pdf. These documents require EPA to competitively bid contracts, with certain exceptions. Following USGS/GLSC withdrawal from the cooperative agreement, the GLNPO took advantage of an existing contract with CSC through USEPA Office of Water to process fish for the National Fish Tissue Study. The GLFMP was able to utilize the existing contract for the GLFMP fish processing. Quality system requirements had already been met by the contractor because it was a pre-existing contract.

Future contracts utilized by the GLFMP will follow the guidelines in the GLNPO QMP and include requirements for the provision of a quality management plan and quality assurance project plans, or other appropriate quality system documentation. The GLFMP Program officer is responsible for ensuring the presence of a well-defined statement of work and for ensuring the presence of quality system documentation that includes reviews or audits.

4.2.3 Special Conditions

The GLFMP Program officer will include any conditions for which project participants must adhere in the assistance agreement. Because the GLFMP assistance agreement for the chemical analyses involves an environmental collection activity, the GLFMP Program officer will also include the required special conditions statement regarding quality systems as described in the GLNPO QMP.

Section 5
Document Control and Records and Information Management

The GLFMP follows the procedures outlined in the GLNPO QMP for maintaining proper document control and records.

5.1 Management of Documents and Records

Historical: The history of document management for the GLFMP is not well known prior to 1991 and because portions of the program were conducted voluntarily, partners were not bound by GLNPO quality requirements. Originally, all Quality Assurance issues for the analytical portion of the Open Lakes Trend Monitoring Program were the responsibility of the Region 5 Central Regional Laboratory and GLNPO does not have copies of these QAPPs readily available. However, details regarding strategic planning, objectives, methods and quality control can be found in several historical EPA documents as well as published manuscripts in scientific journals (See Appendices 2, 3, & 6). The fish processing, analysis, and archiving procedures conducted by USGS/BRD (originally the USFWS) are well documented in SOPs and can be found in Appendix 2. The nearshore program was conducted by the USFDA until 1997, and they followed their own program's methodology and QAPPs, which have been cited earlier in this document.

Current: The GLFMP adheres to strict document and record management. The GLFMP Program officer is responsible for submitting deliverables associated with the GLFMP to GLNPO's document control coordinator for entry into the system. Final reports, QAPPS and other documents associated with the GLFMP are stored in centrally marked files as hard copies and soft-copies are maintained on GLNPO's local area network (LAN) site location (G:\ALL\QA).

5.2 Management of Information

The GLFMP is unique compared to many environmental monitoring programs because of its long term data collection and analysis. Due to the 30 year history of the GLFMP, maintenance of data over time has changed hands and procedures many times. Presently, very strict protocols exist to govern the verification, storage, and release of data collected under the GLFMP. This process was implemented in the fall of 2003 and affected all data beginning in the year 1999.

Historical: Open lake trend monitoring data collected for the years 1991-1998 were not verified under the strict protocols that are currently being implemented, but were verified by the GLFMP Program officer, Sandra Hellman, who worked with partners from the USGS/GLSC to ensure that the data met all of the quality criteria described in the QAPP's during her time at GLNPO. The data is stored in GLENDA and are subject to the same release protocol as the current data. Open lake trend monitoring data for the years prior to 1991, were accepted by the GLFMP Program officer, David DeVault, following data verification by the Region 5 Central Regional Laboratory.

Data collected for the sport-fish monitoring program was verified by USFDA scientists and then submitted to GLNPO with the most pertinent quality assurance information included. The

GLFMP Program officer was responsible for accepting or refusing the data as final. This pre-1991 data was stored as hard copies in filing cabinets.

Current: During the data verification and validation process, the PI submits the data to EPA and the designated QA contractor (Computer Sciences Corporation (CSC)) in the Great Lakes Environmental Monitoring Database (GLENDA) fish tissue reporting standard, which can be found at http://www.epa.gov/glnpo/lmmb/rptstds/index.html. GLENDA is the environmental database developed for GLNPO during the Lake Michigan Mass Balance (LMMB) study to house its environmental monitoring data. CSC then QA/QCs the data and sends the flagged data set to the PI for correction. Each time this process occurs, a different number is assigned by the database manager to the file to track changes. For example, a submission is marked with a 1 and so on. This process repeats until a fully verified data set is established and the GLNPO GLENDA Manager uploads the finalized dataset to GLENDA after he or she conducts an additional QA/AC of the data set. All submissions from the PI are stored on the G drive, G:\DATA\Fish Data. Finally the GLFMP Program officer approves each finalized data set.

All data requests are channeled to the GLFMP Program officer for response. In cases where the database needs to be queried, GLNPO's database manager will be consulted. Data requests will be tracked, including all contact information, so that any later changes made to the database can be forwarded to the appropriate people.

5.3 Data Reporting

The data produced by the GLFMP is of high interest to the general public and to researchers and are available through a request to query the GLENDA database. A list of publications using GLRMP data is available in Appendix 6.

In addition to scientific publication, GLFMP data is used in various governmental reporting venues and in annual reports, including the State of the Lakes Ecosystem Report (SOLEC) and the Binational Toxic Strategy (BTS) semi-annual reporting. Examples of GLFMP reporting can be found in Appendix 6.

Section 6
Quality Assessment and Response

The GLFMP conducts quality assessments to ensure that its quality system is effective at producing data of adequate quality to meet program objectives. These assessments are formal evaluations of performance relative to the pre-determined standards outlined in the GLFMP QMP and QAPPs. Following the evaluation, a response is implemented that provides corrective actions to improve performance where necessary. The GLFMP uses several tools to conduct its evaluations, including: quality systems audits, technical systems audits, field and laboratory audits or "visits", performance evaluations, peer input or program reviews, peer reviews, and data quality assessments.

6.1 Quality Systems Audits and Technical Systems Audits

Historical: Origionally, the U.S. Fish and Wildlife Service (now USGS/GLSC) was responsible for the collection, processing and archiving of environmental samples. The GLFMP Program officer performed frequent "site visits" to ensure that proper protocols were being followed. Following the withdrawal of the U.S. Fish and Wildlife Service from the GLFMP, GLNPO assumed processing and archival responsibilities for GLFMP samples.

Current: The GLNPO Quality Manager works together with the GLFMP Program Officer to conduct periodic audits of the laboratories performing the chemical analyses. These periodic Quality System Audits (QSAs) are led by the GLNPO Quality Manager and include other members of the Region 5 Quality Team, as well as potential contractors as determined by the GLNPO Quality Manager and the GLFMP PO. The purpose of QSAs is to determine the compliance of the GLFMP with its QMP. More information describing these audits can be found in Section 9 of the GLNPO QMP. The GLFMP should conduct a QSA each time a new laboratory takes over the project or once every three years, whichever occurs first.

The GLFMP is one of GLNPO's high profile collection program, and thus is also subject to periodic technical system audits (TSAs) by the GLNPO Quality Management Team. During these audits, all phases of the program, including sample collection, preparation, and analysis are evaluated qualitatively. TSAs are most beneficial at the start of a project. Because the GLFMP is a long term monitoring program, GLNPO should perform a TSA whenever a new laboratory or organization becomes substantially involved in the project. More information on TSAs can be found in Section 9 of the GLNPO QMP.

6.2 Laboratory and Field Audits or "Visits"

The GLFMP Program officer also conducts periodic "site visits" to the field collection teams to ensure adherence to the Sample Collection Activity QAPP. Because there are many teams out collecting fish at approximately the same time of year, the GLFMP Program officer selects different teams to "visit" each year, with the goal of visiting each collection team at least once every five years.

The process of conducting QSAs and "site visits" must be flexible to allow for changes in collection or analytical personnel. For example, certain collection teams may be new or more inexperienced resulting in more frequent "audits" than teams that have been in place for years

and have already demonstrated expertise.

The GLFMP PO, along with the GLNPO Quality Management Team, should plan the audit and document the plan in advance to ensure an organized and successful audit. The important components of an audit plan are documented in the GLNPO QMP in section 9.3. This plan must be shared in advance with the party being audited so that they can be prepared with appropriate documents and available personnel during the audit.

The scope and findings of the audit are documented in a report, along with corrective actions that need to be taken. The party being audited is encouraged to review the report and provide comments before the report is deemed final. The final report is sent to GLNPO management. The GLFMP Program Officer and GLNPO Quality Manager works with the audited party to follow through on all corrective actions identified in the report. All corrective actions taken are added to final audit report. The GLFMP Program Officer and GLNPO Quality Manager determine if any of the corrective actions result in the need to update the GLFMP QMP or QAPPs.

6.3 Performance Evaluations

The GLFMP uses Performance evaluations (PEs) as another tool to evaluate data quality. As mentioned in section 2.3 “check” samples have been used both historically and currently by the GLFMP to ensure consistency with the data over time. This is crucial to the success of a long-term monitoring program. In addition to the check samples, PEs are used when a new laboratory / grantee is awarded the chemical analyses portion of the GLFMP. Before the grant is awarded, several PE samples are sent to the laboratory for analyses. These samples are of known identity and concentrations to GLNPO, but are blind samples to the analyst. The GLFMP Program Officer and GLNPO Quality manager are then able to evaluate the results to determine whether the Data Quality Objectives (DQOs) and Measurement Quality Objectives (MQOs) have been satisfied. The new laboratory will not be sent GLFMP samples until they have successfully demonstrated their ability to analyze the PEs.

Clarkson University completed a successful PE analysis before being awarded the GLFMP grant in 2006, GLFMP Summary of Results for Performance Evaluation (Appendix 1).

6.4 Peer Input

The GLFMP utilizes peer input as a tool to assess and enhance the overall quality of the program and to ensure that the program is meeting the needs of its stakeholders. Peer input has been requested of various scientific and technical experts inside and outside the agency over the course of the GLFMP’s existence. Peer input for the GLFMP has been requested via mail, phone calls and meetings called program reviews. Program review panels can include scientists directly involved with the GLFMP. The goals of these reviews can vary, but they are generally intended to evaluate whether the current program is sufficiently able to meet the needs of its stakeholders and. The most recent program review of the GLFMP was held in the spring of 2005, see GLFMP Review Final Report 2005 (Appendix 3).

6.5 Peer Review

Formal peer reviews play a very important role in the GLFMP and provide an in-depth assessment of the data that looks at assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria and conclusions.. EPA has a formal Peer Review Policy that requires reviews to be conducted for all major scientific products. The GLFMP is one of GLNPO's most significant monitoring programs and the data is used by EPA, other government agencies and environmental groups as an indicator of the health of the Great Lakes. Thus peer reviews must be conducted periodically to evaluate the program. In a formal peer review, there is an independent third-party review of the program from experts who do not have a material stake in the outcome of the review. One of the main goals of the peer review process is to evaluate the data collected by the program and then determine if the quality of the data is sufficient to meet the objectives of the program. The EPA Scientific Peer Review Handbook can be found at: http://www.epa.gov/osa/spc/pdfs/prhandbk.pdf. Peer reviews result in a written report produced by the review team and containing recommendations for potential changes to the program.

6.6 Data Quality Assessments

Data Quality Assessments occur at several different levels in the GLFMP. As previously described in Section 5.2, each dataset is submitted to a rigorous QA/QC process before it can be entered into the GLENDA database. Data quality audits are an additional tool used to assess the quality of the data being collected. Potential PI's are required to submit sample data sets in the GLENDA reporting format prior to receiving actual sample so that potential data issues can be evaluated and then addressed during the audit.

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Support Documents

- DFO Contaminants Surveillance Program Associated Publications (1991 – 2005)
- A Synthesis of Ecological and Fish – Community Changes in Lake Ontario, 1970 – 2000
- Extremes of Lake Ontario Lake Trout Migration Patterns By Age
- Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory

Appendices

Appendix 1 – Current GLFMP Quality Documentation

- GLFMP Quality Assurance Project Plan for Collection Activities
- Clarkson University Draft QMP for Chemical Analysis of Fish Tissue for GLFMP
- Axys Lab Report of the Fish Sample Homogenization Audit
- Clarkson Laboratory Site Visit Report 2006 - Final
- GLFMP Summary of Results for Performance Evaluation – Clarkson University 2006
- GLNPO QMP

Appendix 2 – Historical GLFMP Quality Documentation

- University of Minnesota GLFMP QAPP V. 7
- FDA Comprehensive Residue Analysis Report for EPA FDA Survey
- Identification of Organic Compounds in Great Lakes Fishes by Gas Chromatography/Mass Spectrometry: 1977
- Quality Assurance Project Plan for EPA/IAG Title: Monitoring Trends of Selected PCB Congeners and Pesticides in Fish from the Great Lakes, 1991, 1992, and 1993
- Workshop on Identifying Emerging Contaminants for Fish Contaminant Monitoring Programs Final Report - 2001
- Laboratory Site Visit Report University of Minnesota March 6 - 7, 2003
- Concentration of PCBs, Trans nonachlor, and Total Mercury in Biota Samples Collected for the Lake Michigan Mass Balance Study
- Great Lakes Fish Monitoring Program Data Quality Objective Revision report - 2005
- Fish Processing Method – Standard Operating Procedure SOP No. HC 523A.SOP
- 1983 FDA Pesticide Analysis Method and Personal Note

Appendix 3 – GLFMP Program Design Documents and Significant Reports

- Fish Monitoring Program Summary - 1982
- A Great Lakes Perspective, June 1982
- Contaminants Surveillance Program for the Great Lakes, Rational and Design
- Evaluating presence and effects of contaminants in fish in the Great Lakes – 1982
- USGS/BRD EPA – GLNPO Fish Collection Cooperative Agreement
- USGS/BRD Cooperative Agreement Withdrawal Memo
- Fish Consumption Advisories for the Great lakes report 1983
- Eutrophication/Nutrient Monitoring Program – Great Lakes International Surveillance Program 1982
- Trends in Great Lakes Fish Contaminants report V. 4
- GLFMP Program Review Final Report - 2005
- Contaminants in Upper Great Lakes Fishes - 1975
- Great Lakes International Fish Contaminants Surveillance Program Design
- Program Design Maps
    - Collector locations atmospheric dep. and acid rain monitoring network
    - Significant Areas of Concern 1982
    - Open Lake Tributary and Harbor Mouth Collection Sites 1980 – 82
    - Fish Collection Sites

- Cooperative Agreement Templates
    - State Agency
    - Federal Agency

Appendix 4 – GLFMP Significant Events

- GLFMP Significant Events

Appendix 5 – GLFMP Collection Information

- Collection Change Information
    - Top Predator notes and analytes
    - Sport Fish notes and analytes
- Collection Grid Maps
    - GLFMP Sampling Stations Map
    - Lake Superior Grid Map
    - Lake Michigan Grid Map
    - Lake Huron Grid Map
    - Lake Erie Grid Map
    - Lake Ontario Grid Map
- Collector Information
    - Collector Contacts
    - Collection Grants and IAGs

Appendix 6 – GLFMP Publications

- GLFMP Reporting Examples

- Batterman, S., S. Chernyak, E. Gwynn, D. Cantonwine, C. Jia, L. Begnoche, and J.P. Hickey. 2007. Trends of brominates diphenyl ethers in fresh and archived Great Lakes Fish (1979 - 2005). Chemosphere. 69. 444 - 457.

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